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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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09/155,327 03/29/99 CORY

S 11686

EXAMINER

HM22/0409

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ART UNIT

PAPER NUMBER

1633

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Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

# Office Action Summary

Application No.

09/155,327

Applicant(s)

CORY ET AL.

Examiner

Sumesh Kaushal

Art Unit

1633

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 22 January 2001.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1-4 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-4 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claims \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are objected to by the Examiner.
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved.
- 12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. § 119

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

## Attachment(s)

- 15) ☐ Notice of References Cited (PTO-892)
- 16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 17) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_\_.
- 18) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_.
- 19) ☐ Notice of Informal Patent Application (PTO-152)
- 20) ☐ Other: \_\_\_\_\_.

### DETAILED ACTION

Applicant's response filed on 01/22/01 have been fully considered but is found unpersuasive for the reasons of record as set forth in the earlier office action (Paper No.15, 07/17/00). Claims 5-20 are canceled by the applicant. Claims 1-4 are amended and are examined in this office action.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

#### *Claim Rejections - 35 USC § 112*

Claims 1-4 stand rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for an isolated nucleic acid consisting of SEQ ID NO: 6 and 8 encoding the amino acid sequences of SEQ ID NO: 7 and 9, does not reasonably provide enablement for an isolated nucleic acid comprising any and all derivatives of SEQ ID NO: 6 and 8, which has 47% or greater similarities to the amino acid sequence of SEQ ID NO: 7 and 9, or derivatives thereof and wherein the protein enhances cell survival. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims, for the same reasons of record as set forth in the official action mailed on 07/17/00.

The applicant argues that nucleic acid molecules of claims 1-4 as amended do not include all derivatives or sequences that share similarities to SEQ ID NO:6 or 8 but include those derivatives and homologs sequences that enhances cell survival. The applicant further argues that human Bcl-w and murine Bcl-w share about 90% similarity. The applicant concluded that those skill in the art can isolate a nucleic acid molecule that hybridize to SEQ ID NO:6 or 8, or encodes a protein that share at least about 47% similarity to SEQ ID NO: 7 or 9, and determine whether the isolated molecule enhances cell survival (response, page 4, para. 2).

Art Unit: 1633

However, this is not found persuasive because the specification only disclosed SEQ ID NO: 6 and 8 that encodes the Bcl-w polypeptide that enhances cell survival. The specification as filed fails to disclose that any derivative of nucleic acid sequence of SEQ ID NO: 6 and 8 that encodes a polypeptide having at least 47% or greater similarities to the amino acid sequence of SEQ ID NO: 7 and 9, or derivatives thereof and the protein enhances cell survival. It is known in the art that the bcl-2 signaling pathways are complex and have very divergent functions (specification page 2, line 4-25). The specification as filed fails to disclose any derivative of SEQ ID NO: 6 and 8 that enhances the survival of any cell by inhibiting programmed cell death. The claimed derivatives are simply computer-generated hypotheses, wherein no biological function has been established. There is no description of mutational sites that exist in nature and there is no description of how the structure of putative Bcl-w derivatives relates to the structure and function of Bcl-2 related genes. It is general knowledge in the art that even conservative amino acid substitutions can adversely affect proper folding and biological activity if amino acids that are critical for such functions are substituted. The relationship between the sequence of a polypeptide and its tertiary structure is neither well understood nor predictable. The recited SEQ ID NO(s) are simply computer-generated hypothesis because no biological function has been established. The mere identification of critical regions would not be sufficient, as the ordinary artisan would immediately recognize that the encoded polypeptide must assume the proper three-dimensional configuration to be active, which is dependent upon the surrounding residues. The applicant has not presented enablement commensurate in scope with the claims and it is not clear how one skilled in the art would use the derivatives as claimed for any specific purpose.

In view of the fact that there is no specific guidance or teaching for such in the specification as filed, it would require undue experimentation to practice the claimed invention. The quantity of experimentation required would include the functional characterization of any and all derivatives of SEQ ID NO: 6 and 8 which has 47% or greater similarities to the amino acid sequence of SEQ ID NO: 7 and 9, or derivatives thereof and the role of deduced amino acid sequences as cell survival activity.

***Claim Rejections - 35 USC § 102***

Claims 1 and 4 stand rejected under 35 U.S.C. 102(e) as being anticipated by Guastella (US 5,789,201 07/04/1998, *of record*). Guastella teaches nucleotide sequences encoding a bcl-2 homolog (bcl-y) which matches 97.4% to SEQ ID NO: 6, 98.7% to SEQ ID NO: 7, 85.65 to SEQ ID NO:8 and 96.9% to SEQ ID NO:9 (see PTO sequence search report). Thus, the cited art anticipate the invention of instant claims.

The applicant argues that the present inventors reduced the claimed invention practice in Australia prior to January 1996. As evidence the applicant provided the sequence entered into the mainframe computer at Walter and Eliza Hal institute prior to January 1, 1996 (response, page 5, para. 3; Exhibit A and B).

The applicant response and Exhibits A and B are fully considered. However, this is not found persuasive because the identity of Exhibits A and B is unclear. In addition, the applicant fails to execute a declaration under 37CFR 1.131 to over come prior art rejection. Thus, the instant claims stand rejected under 35 USC 102(e) as anticipated by the cited art.

***Conclusion***

No claims are allowed.

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a). A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any

Art Unit: 1633

extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sumesh Kaushal Ph.D. whose telephone number is (703) 305-6838. The examiner can normally be reached on Monday-Friday from 9:00 AM to 5:30 PM. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor Deborah Clark can be reached on (703) 305-4051. The fax-phone number for the organization where this application or proceeding is assigned as (703) 308-4242. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the patent analyst Tracey Johnson, whose telephone number is (703) 308-0377. If the claims are amended canceled and/or added the applicants are advised to follow Amendment Practice under 37 CFR § 1.121 (<http://www.uspto.gov>).

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